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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,962	11/13/2006	Richard Joseph Fagan	C&R-106	6818
23557 7590 01/26/2009 SALIWANCHIK LLOYD & SALIWANCHIK A PROFESSIONAL ASSOCIATION PO Box 142950 GAINESVILLE, FL 32614				
EXAMINER				
SAOUD, CHRISTINE J				
ART UNIT		PAPER NUMBER		
1647				
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01/26/2009		PAPER		

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/539,962

Applicant(s)

FAGAN ET AL.

Examiner

Christine J. Saoud

Art Unit

1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 April 2008.
2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 67-88 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 67, 74-78 and 85-88 is/are rejected.
7) ☒ Claim(s) 68-73, 79-84 is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date 5/14/07
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I in the reply filed on 13 December 2007 is acknowledged. The traversal is on the ground(s) that the claims are linked by a special technical feature, specifically SEQ ID NO:8 and 10, wherein SEQ ID NO:10 is the mature form of SEQ ID NO:8. This is not found persuasive because the original claims were not so limited to a particular amino acid sequence, but rather included "a functional equivalent". Based on that limitation in claim 46, the technical feature of the independent invention was a human placental growth hormone, which was known in the art and therefore, did not constitute an advance over the prior art.

However, the newly submitted claims of 13 December 2007 are limited to a polypeptide comprising SEQ ID NO:8 or 10, fragments thereof with activity and polypeptides that have greater than 85% identity to SEQ ID NO:8 or 10. Because SEQ ID NO:8 and 10 are related in that one sequence has a signal sequence component compared to the other, the search and examination of both embodiments would not be burdensome and the restriction requirement between the two molecules is withdrawn.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on 14 May 2007 is in compliance with the provisions of 37 CFR 1.97 and has been considered by the examiner.

The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 67, 74-77 are rejected under 35 U.S.C. 102(b) as being anticipated by Cooke et al. (J. Biol. Chem. 263 (18): 9001-9006, 1988).

Cooke et al. teach a growth hormone molecule from the placenta which shares more than 85% amino acid identity with that of SEQ ID NO:8 and 10 of the instant claims. The molecule of Cooke et al. (hGH-V) is shown in Figure 3 and the protein was

isolated as evidenced by Figure 4. Therefore, Cooke et al. anticipates the instant claims.

Claims 67, 74-78 and 85-88 are rejected under 35 U.S.C. 102(b) as being anticipated by US Pat. No. 5,597,709 (Rosen et al.).

Rosen et al. teach a growth hormone molecule from the placenta which shares more than 85% amino acid identity with that of SEQ ID NO:8 and 10 of the instant claims. Rosen et al. teach the isolated protein as well as compositions of the protein with a pharmaceutically acceptable carrier (see column 9, lines 40-47) and Figure 2. Therefore, Rosen et al. anticipates the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 78 and 85-88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cooke et al. (J. Biol. Chem. 263 (18): 9001-9006, 1988).

The disclosure of Cooke et al. is as described above. Cooke et al. does not teach compositions of hGH-V comprising the protein and a pharmaceutically acceptable carrier. However, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to make a composition comprising the protein of Cooke et al. with a pharmaceutically acceptable carrier for the purpose of studying the

functional activity of the protein of Cooke et al. Cooke et al. teach that the protein is a variant of growth hormone produced in the placenta, therefore, it is expected to be a protein that regulates growth. Therefore, one of ordinary skill in the art at the time the invention was made would have been motivated to put the protein in a composition which comprises a pharmaceutically acceptable carrier to study the activity of the protein in vivo. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, absent evidence to the contrary.

SEQ ID NO:10

```
Query Match          95.0%; Score 853; DB 1; Length 217;
  Best Local Similarity 87.4%; Pred. No. 2.2e-71;
  Matches 167; Conservative 4; Mismatches 2; Indels 18; Gaps 1;

Qy      1  FPTIPLSRFLFDNAMLRRRLYLQAYDTYQEFVSSWVM-----ESIPT 42
      |||
Db      27  FPTIPLSRFLFDNAMLRRRLYLQAYDTYQEFEEAYILKEQKYSFLQNPQTSLCFSES IPT 86

Qy      43  PSNRVKTQQKSNLELLRISLLLIQSWLEPVQLLRVFNANSLVYGASDSNVYRHLKDLEEG 102
      |||
Db      87  PSNRVKTQQKSNLELLRISLLLIQSWLEPVQLLRVFNANSLVYGASDSNVYRHLKDLEEG 146

Qy     103  IQTLMWRLEDGSPRTGQIFNQSYSKFDTKSHNDDALLKNYGLLYCFRKDMDKVETFLRIV 162
      |||
Db     147  IQTLMWRLEDGSPRTGQIFNQSYSKFDTKSHNDDALLKNYGLLYCFRKDMDKVETFLRIV 206

Qy     163  QCRSVEGSCGF 173
      |||
Db     207  QCRSVEGSCGF 217
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SEQ ID NO:8

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Query Match          95.6%; Score 982; DB 1; Length 217;
  Best Local Similarity 88.9%; Pred. No. 2.3e-81;
  Matches 193; Conservative 4; Mismatches 2; Indels 18; Gaps 1;

Qy      1  MAAGSRTSLLLAFLGLCLSLWQEGSAFPTIPLSRFLFDNAMLRRRLYLQAYDTYQEFVSS 60
      |||
Db      1  MAAGSRTSLLLAFLGLCLSLWQEGSAFPTIPLSRFLFDNAMLRRRLYLQAYDTYQEFEEA 60

Qy     61  WVM-----ESIPTPSNRVKTQQKSNLELLRISLLLIQSWLEPVQLLR 102
      |||
Db     61  YILKEQKYSFLQNPQTSLCFSES IPTPSNRVKTQQKSNLELLRISLLLIQSWLEPVQLLR 120
```

Qy 103 SVFANSLVYGASDSIVYRHKLPLEEGIQTLMWRLEDGSPRTGGIFNQSYSKFDTKSHNDD 162
Db 121 SVFANSLVYGASDSIVYRHKLPLEEGIQTLMWRLEDGSPRTGGIFNQSYSKFDTKSHNDD 180

Qy 163 ALLKNYGLLYCFRKMDKVKETFLRIVQCRSVEGSCGF 199
| | | | |
Db 181 ALLKNYGLLYCFRKMDKVKETFLRIVQCRSVEGSCGF 217

Claims 68-73 and 79-84 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christine J. Saoud whose telephone number is 571-272-0891. The examiner can normally be reached on Monday-Friday, 6AM-2PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christine J Saoud/
Primary Examiner, Art Unit 1647